AWARD NUMBER: W81XWH-15-1-0518

TITLE: Comparing Running-Specific and Traditional Prostheses during Running: Assessing Performance and Risk

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REPORT DATE: September 2016

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	**2. REPORT TYPE**	**3. DATES COVERED**
September 2016	Annual	1 Sep 2015 - 31 Aug 2016

4. TITLE AND SUBTITLE Comparing Running-Specific and Traditional Prostheses During Running: Assessing Performance and Risk

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-15-1-0518

5c. PROGRAM ELEMENT NUMBER

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Our current knowledge of individuals with lower extremity amputation (ILEA) running is limited with respect to biomechanical performance and injury risks. ILEA are able to run with both running specific prostheses (RSPs) and traditional prostheses (TPs); however, direct comparisons of subjects running with each of these prosthetic designs do not exist. Furthermore, no ILEA running studies to date have investigated muscle activities, nor have running simulations of musculoskeletal models been generated. These major gaps in research substantially limit our understanding of both performance and injury risk of ILEA running with different prosthetic designs. Gaining this knowledge will directly inform clinicians on prosthesis prescription for running at a range of speeds as well as for return to duty scenarios. Therefore, the purpose of this study is to utilize motion capture, muscle activity, and musculoskeletal modeling techniques to directly compare performance and injury risks of ILEA running with both RSPs and TPs across a range of speeds. The scope of this study covers ILEA with unilateral transtibial amputations who are able to run. Data collection has not begun due to delays in both the HRPO approval process and the registration process on clinicaltrials.gov. However, these delays are not expected to impact the overall completion date of the study.

15. SUBJECT TERMS
Kinetics, biomechanics, amputation, prosthesis, transtibial

16. SECURITY CLASSIFICATION OF: U			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON** USAMRMC
a. REPORT Unclassified	**b. ABSTRACT** Unclassified	**c. THIS PAGE** Unclassified	Unclassified	11	**19b. TELEPHONE NUMBER** *(include area code)*

Table of Contents

Page

I. INTRODUCTION

Our current knowledge and understanding of individuals with lower extremity amputation (ILEA) running is limited with respect to biomechanical performance and injury risks. ILEA are able to run with both running specific prostheses (RSPs) and traditional prostheses (TPs); however, direct comparisons of subjects running with each of these prosthetic designs do not exist. The varying reported literature examining one design or the other often does not have participants running at the same velocities. Additionally, when running velocities are similar between studies, the same variables are rarely investigated. This makes comparisons between RSPs and TPs exceedingly difficult to compare directly, and drawing conclusions on both performance and injury risk is virtually impossible. Furthermore, no ILEA running studies to date have investigated muscle activities, nor have running simulations of musculoskeletal models been generated. These major gaps in research substantially limit our understanding of both performance and injury risk of ILEA running with different prosthetic designs. Gaining this knowledge will directly inform clinicians and administrators within the DOD and VA systems on prosthesis prescription for running at a range of speeds as well as for return to duty scenarios. Therefore, the proposed study will utilize motion capture, muscle activity, and musculoskeletal modeling techniques to directly compare performance and injury risks of ILEA running with both RSPs and TPs across a range of speeds. We will also capture an able-bodied control group for normative comparisons. In doing so, this project directly attends to the OPORA's goals and needs at multiple levels.

II. KEYWORDS

Kinetics, biomechanics, amputation, prosthesis, transtibial

III. ACCOMPLISHMENTS

A. What were the major goals of the project?

A group of military, veteran, and/or civilian individuals, who have sustained lower extremity amputations due to trauma, cancer, or congenital reasons and who have been prescribed RSPs will be recruited to:

1. compare RSPs and TPs with respect to running ability and performance; and
2. compare RSPs and traditional prostheses with respect to injury risks associated with running.

Within both of these goals, a matched control group of able-bodied runners will be tested to compare running ability and performance and injury risks.

Project milestones, along with target completion dates and percentage completion are shown in the table below.

MAJOR TASKS	MILESTONES	TARGET COMPLETION DATES	PERCENTAGE COMPLETION
TASK 1: Prepare regulatory documents and research protocol for study	1.1 Obtain local IRB approval at Regis and Colorado School of Mines	Nov 15, 2015	100%
	1.2 Obtain HRPO approval for all protocols and local IRB approval through Regis	June 27 2016	100%
TASK 2: Coordinate equipment and study staff for trials	2.1.1 Research staff hired	May 17 2016	100%
	2.1.2 Research staff trained	Aug 2016	100%
	2.2.1 Purchase and install instrumented treadmill	Mar 16 2016	100%
	2.2.2 Purchase and install motion capture system	Nov 11 2015	100%
	2.2.3 Purchase and install electromyography (EMG) system	Dec 1 2015	100%
Task 3: Comparative effectiveness research study	3.1.1 One participant consented, screened, and enrolled	April 2016	30%
	3.2.1 Preliminary data analysis of running performance (complete 1 analysis)	Aug 2016	0%
	3.2.2 Preliminary data analysis of running injury risk (complete 1 analysis)	Aug 2016	0%

B. What was accomplished under these goals?

1. Major Activities
   a. Milestone T1.1 was achieved in Year 1, Quarter 1.
      i. The Regis University IRB approved the initial submission on Nov 15, 2016, and the amendment/modification of the protocol on May 10, 2016.
      ii. On Jan 27, 2016, the Colorado School of Mines (CSM) signed the IRB Authorization Agreement, which relinquished oversight of IRB review and human subject protection to the Regis University IRB.
   b. Milestone T1.2 was achieved in Year 1, Quarter 4.
      i. Regulatory documents and local IRB approval documents were submitted to HRPO for approval initially in Year 1, Quarter 2 and resubmitted in Year 1, Quarter 3 as requested by HRPO. The need to resubmit documentation in Year 1, Quarter 3 resulted in a delay in receiving HRPO approval, which occurred in Year 1, Quarter 4 rather than Year 1, Quarter 2.
   c. Milestones T2.1.1 and T2.1.2 were achieved in Year 1, Quarter 4.

i. The Research Coordinator position was filled and training on the financial management system was completed.
ii. The PhD graduate student reported to campus during Year 1, Quarter 3 and completed training on the instrumented treadmill, motion capture, and EMG systems in Year 1, Quarter 4.

d. Milestones T2.2.1, T2.2.2, and T.2.2.3 were achieved in Year 1, Quarters 2 and 3.
i. The instrumented treadmill was installed on Mar 16, 2016 (Year 1, Quarter 3).
ii. The other two required systems, motion capture and EMG, were installed during Year 1, Quarter 2.

e. Milestone T3.1.1
i. Meeting this milestone was delayed because of the delay in receiving HRPO approval, and the subsequent delay in registering the study on clinicaltrials.gov. This later task required an additional six weeks to complete.
ii. Coordination with Sites for flow charts is ongoing with 85 percent completed.
iii. Preliminary data collections to ensure accurate data are being generated have been completed and protocols are being practiced to ensure adequate implementation during actual data collection sessions.
iv. The study was registered on the website, clinicaltrials.gov, during Year 1, Quarter 4.
v. The model for the Visual 3D analyses was developed.
vi. The musculoskeletal model for the muscle and joint force analyses was partially developed (10 percent).
vii. Techniques for collecting and analyzing EMG data were developed.
viii. Additional lab setup has been required based on preliminary data collection sessions. These sessions showed a loss of motion analysis data because of interference by the treadmill hand rails and harness system. Efforts are being made to modify camera placement to minimize loss of data, and to investigate alternate harness systems. Camera wall mounts have been designed and fabricated that will allow for adjustments in camera location to maximize signal detection from the motion sensors.

2. Specific Objectives
None

3. Significant or Key Outcomes
None

4. Other Achievements
None

This project is on time and meeting the goals and accomplishments set for the first year with two exceptions. Because of the delay in obtaining HRPO approval and the subsequent delay in registering this study on clinicaltrials.gov, subject recruitment was not initiated according to the proposed schedule. Consequently, the testing of the first participant has not been completed. Subject recruitment will begin during Year 2,

Quarter 1. This delay in subject recruitment and subsequent testing of the first subject is not expected to impact the overall completion date of the study.

C. What opportunities for training and professional development has the project provided?

All Project staff completed the required Collaborative Institutional Training Initiative (CITI) training. In addition, the graduate student received training on operating test equipment, data collection methodologies, and laboratory management. This individual also attended the 40th Annual Meeting of the American Society of Biomechanics, held in Raleigh, North Carolina, August 2-5, 2016. (This training was not funded by this grant.) The Research Coordinator received training related to the Regis University financial management system and laboratory management. The Principal Investigator also received training for grant management and collaborative project management involving multiple universities.

D. How were the results disseminated to communities of interest?

Nothing to report.

E. What do you plan to do during the next reporting period to accomplish the goals?

During the next reporting period (Year 2, Quarter1), we plan to do the following in order to accomplish the goals and objectives of this project:

1. Major Task 3 (Subtask 1)
    a. Continue to prepare the laboratory for this study by:
        i. Installing camera wall mounts and determining optimum camera positions for collecting motion data.
        ii. Installing harness and rail system for treadmill.
    b. Initiate subject recruitment.
        i. Solicit subjects who will be participating in a running clinic that will be held on September 10, 2016 at the Colorado School of Mines.
        ii. Contact prosthetic and therapy clinics and distribute flyers soliciting study participants.
    c. Coordinate with all key personnel to modify the project flow chart if needed
    d. Make any necessary modifications to the model for the Visual3D analysis.
    e. Make any necessary modifications to the techniques for EMG analysis.
    f. Continue development of the musculoskeletal model for muscle and joint force analysis.
    g. Complete the testing of 1 to 6 subjects.
2. Major Task 3 (Subtask 2)
    a. Complete data analysis for 1 to 2 subjects.

IV. Impact

Nothing to report.

V. Changes / Problems

A. Changes in approach and reasons for changes.

Nothing to report.

B. Actual or anticipated problems or delays and actions or plans to resolve them.

Approval of the protocol by HRPO was delayed by approximately four months. Another 1.5 months were required to register the study on clinicaltrials.gov. These two delays postponed subject recruitment efforts from March 2016 to August 2016. Additional recruitment efforts will be made during Year 2, Quarter 1 to identify potential subjects participating in a running clinic being held at the Colorado School of Mines and by contacting local clinics providing prosthetic devices.

C. Changes that had a significant impact on expenditures.

There was an eight-month delay in filling the research coordinator position, which resulted in a savings in salary during the first year of the grant. However, a higher level of effort for this position may be required during the second year of the grant, because subject testing will be initiated and conducted at a higher rate than planned to make up for the delay in subject recruitment and testing that occurred during the first year of the grant.

Savings also occurred with a lower purchase price for the Visual3D software licenses. This cost savings have been offset by additional costs associated with equipment needs not included in the budget. For example, a set of stairs was needed to safely step up and down from the treadmill, and camera wall mounts had to be designed, fabricated, and installed for the motion capture system. Additional costs will most likely be incurred to modify the treadmill harness system for the purpose of reducing interference with the collection of motion analysis data.

D. Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents.

Nothing to report.

E. Significant changes in use or care of human subjects.

Nothing to report.

F. Significant changes in use or care of vertebrate animals

Not Applicable.

G. Significant changes in use of biohazards and/or select agents.

Not Applicable.

VI. Products

Nothing to report.

VII. Participants & Other Collaborating Organizations

A. What individuals have worked on the project?

Name:	Brian S. Baum, PhD
Project Role:	Principal Investigator
Researcher Identifier (ORCID):	0000-0003-0692-1962
Nearest person month worked:	2
Contribution to Project:	Dr. Baum has performed work in all aspects of the project to date. He has managed preparing regulatory documents and the research protocol for project, and coordinating equipment and project staff for the trials.

Name:	Erika Nelson-Wong, PT, PhD
Project Role:	Co-Investigator
Nearest person month worked:	1
Contribution to Project:	Dr. Nelson-Wong has performed work in assisting with preparing regulatory documents and the research protocol, developing the EMG techniques for data collection, and coordinating equipment and project staff for the trials.

Name:	Anne K. Silverman, PhD
Project Role:	Co-Investigator
Nearest person month worked:	1
Contribution to Project:	Dr. Silverman performed work in assisting preparing regulatory documents and the research protocol for project, and coordinating project staff for the trials.

Name:	Janet Torma-Krajewski, PhD
Project Role:	Research Coordinator
Nearest person month worked:	1
Contribution to Project:	Dr. Torma-Krajewski participated in training sessions, registered the study on clinicaltrials.gov, prepared quarterly and annual project reports, and completed several activities associated with coordinating project tasks.

Name:	Lauren Sepp
Project Role:	Researcher – Graduate Student
Nearest person month worked:	2
Contribution to Project:	Ms. Sepp participated in training sessions and conducted several preliminary testing sessions for implementing the protocol and developing models (Visual3D Analysis and Musculoskeletal models).

B. Has there been a change in the active other support of the PD/PI (s) or senior/key personnel since the last reporting period?

Nothing to report.

C. What other organizations were involved as partners?

Organization Name: Colorado School of Mines (CSM)
Location of Organization: Golden, Colorado
Partner's contribution to the project: Collaboration. Dr. Silverman, project Co-Investigator, is a faculty member of CSM and is leading efforts from that site. The graduate student responsible for data collection and analysis is a student at CSM.

VIII. Special Reporting Requirements

An updated Quad Chart is provided as an attachment.

IX. Appendices

None

Comparing Running-Specific and Traditional Prostheses during Running: Assessing Performance and Risk

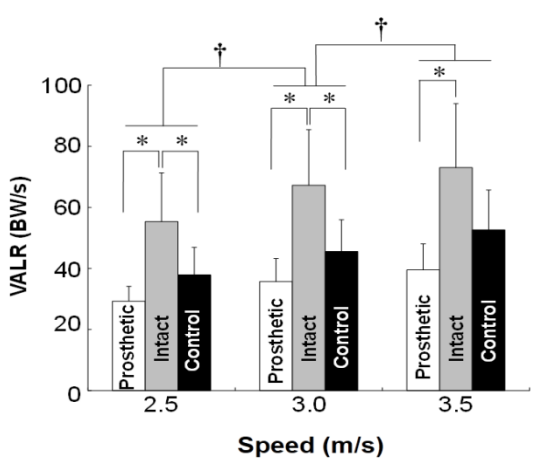
PI: Baum, Brian S. **Org:** Regis University **Award Amount:** $697,999

Study Aims

- Compare running-specific prostheses (RSPs) and traditional prostheses with respect to running ability and performance
- Compare RSPs and traditional prostheses with respect to injury risks associated with running

Approach

- 3D motion analysis and EMG of amputee and able-bodied running on treadmill instrumented with force platforms
- Amputees to run in RSP and traditional prostheses
- Running velocities of 2.5, 3.0, 3.5, 4.0, 5.0, 6.0 m/s (randomized)
- Maximal effort 50m dash to determine top running speed
- Performance outcomes: average ground reaction forces (GRF), joint power output, joint and limb mechanical work
- Injury risk outcomes: limb loading rates, average GRFs, asymmetrical joint forces and moments
- Musculoskeletal modeling with kinetics and EMG to improve estimates of joint loading



A typical RSP

A typical traditional prosthesis

Preliminary data showing injury risk predictor variable vertical average loading rate (VALR) for 8 amputees running with RSPs vs able-bodied runners at 2.5, 3.0, and 3.5 m/s. An asterisk (*) indicates statistically significant differences between limbs at $p < 0.05$. A dagger (†) indicates differences between running speeds at $p < 0.01$.

Timeline and Cost

Activities FY	15 -16	16-17	17-18
Equipment installation and validation			
Subject recruitment, data collection			
Musculoskeletal modeling			
Data analysis, submit publications and follow-up grants			
Estimated Budget ($K)	**$367**	**$164**	**$168**

Updated: Aug 31, 2016

Goals/Milestones

FY15-16 Milestones

- ☐ Equipment Procured, Motion Capture and EMG systems installed
- ☐ Local IRB approval granted; HRPO approval granted; trial registered on clinicaltrials.gov
- ☐ Equipment accuracy validated
- ☐ Recruitment pools (VA, prosthetic clinics, etc.) established
- ☐ Preliminary analysis of performance and risk data completed
- ☐ Data Collection not yet begun

FY16-17 Goals–Data Collection, Preliminary Data Analysis, Verify Modeling

- ☐ Verify musculoskeletal modeling for amputee running
- ☐ Complete 90% of subject testing

FY17-18 Goals–Complete Data Collection, Musculoskeletal Modeling

- ☐ Complete subject testing and data analysis
- ☐ Submit at least 3 manuscripts for publication
- ☐ Prepare follow-up grant submission to DOD and/or NIH